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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,236	04/19/2001	David Geraint Owen	07203.0024	6215

7590

12/31/2002

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,236

Applicant(s)

OWEN ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 and 46 is/are pending in the application.
- 4a) Of the above claim(s) 29-38 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (Claims 1-28) in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 29-38 and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

3. Claims 1-28 (Group I) are treated on the merit in this Office Action.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless

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the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

6. Claims 20-21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Because claims 20-21 are intended use claims and not a positive limitation of the structure of claim 1 from which it depends. Therefore, claims 20-21 does not further limit the subject matter of a previous claim.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) The phrase “high resistance seal” of Claim 1 is vague and indefinite because it is unclear as to what is it resisting. Chemical? Water? Ion? Or Electrical?
- b) The term “screen” is vague and indefinite because it is unclear of its intended meaning for it could imply a process (i.e. a screening process) or a physical entity (i.e. a sieve).
- c) The term “can be” in Claim 3 is vague and indefinite because it is unclear if the ion channel or transporter is actually inserted in the cell membrane.
- d) The term “capable of” in Claims 10 and 26 is vague and indefinite. It is unclear if the device is actually does what it is claimed. That is, does the “contiguous layer of cells”

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adhere to the substrate? And does the "recording head" move to visit each chamber sequentially.

e) Claim 20 is vague and indefinite because it is an intended use and not a positive limitation of the structure of claim 1 from which it depends.

f) Claim 21 is vague and indefinite because it is an intended use and not a positive limitation of the structure of claim 1 from which it depends.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. Claims 1, 4, 6, 8, 11-12 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Osman et al. (US Patent 5,234,566).

Osman et al. disclosed a biosensor comprising at least one lipid membrane (biological membrane) each including a least one gated ion channel having a conductance, which is dependent upon an electric field applied across the membrane (col. 1, lines 49-55) (referring to claims 1, 4, 6, and 20-22). The ion channels are incorporated in the lipid membranes (col. 5,

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lines 6-22). In a two dimensional array, the lipid membrane is formed directly on the substrate surfaces and is directly coupled to the electrode (col. 8, lines 17-31). Wells are made over each element of the array (col. 8, lines 28-31). The substrate is made of materials such as glasses (col. 8, lines 32-35). Therefore, the biosensor of Osman et al. anticipates the presently claimed invention.

11. Claims 1, 9, 19, and 22-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Kovacs et al. (US Patent 5,981,268).

Kovacs et al. disclose a biosensor comprising a layer of cells adhering to the surface of the microelectrode array on an integrated device (col. 7, lines 25-40; fig. 3) (claims 1 and 22). The biosensor monitors the activation of voltage-gated ion channels (col. 4, lines 3-7). The ion measure includes potassium and sodium (col. 14, lines 19-22). The substrate comprise of material such as glasses and polymer (col. 13, lines 20-23). The array of electrodes would also be on a substrate of multiwell plates (col. 13, lines 49-50). The activity of the cellular ion channels and the action parameters of the cell are monitor as a result of their effect on the impedance measured between each microelectrode and the reference electrode (col. 9, lines 26-29). Therefore, the biosensor of Kovacs et al. anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1, 13, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osman et al. (US Patent 5,234,566) in view of Fare et al. (US Patent 5,225,374).

The biosensor of Osman et al. applied for the reasons discussed above.

The biosensor of Osman et al. does not expressly disclose that the substrate is perforated.

Fare et al. disclose a biosensor comprising a lipid bilayer that adheres to the porous substrate forming a high impedance seal (col. 3, lines 16-20; col. 4, lines 35-47). The pore size is from 1 to 1000 nm (col. 5, lines 24-32) (referring to claims 15-17). This would provide a surface for the lipid bilayer to adhere to without defects and tears to the lipid bilayer (col. 2, lines 41-43; col. 5, lines 34-35).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a perforated substrate as taught by Fare et al. in the biosensor of Osman et al. One of ordinary skill in the art would have been motivated to include a perforated substrate in the biosensor of Osman et al. for the advantage of providing a surface for the lipid

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bilayer to adheres to without defects and tears to the lipid bilayer (Fare: col. 2, lines 41-43; col. 5, lines 34-35). Since both Osman et al. and Fare et al. disclose a lip membrane biosensor (Osman: col. 1, lines 49-55; Fare: col. 3, lines 16-20; col. 4, lines 35-47).

15. Claims 1-10, 14, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olesen et al. (US Patent 6,063,260) in view of Stephens et al. (*Journal of Physiology*, 1994, 477(2):187-196).

Olsen et al. disclose a high throughput patch clamp apparatus (Abstract). The patch clamp comprise of a membrane ion channel of a cultured cell, which is position on a coverslip (col. 9, lines 57-67). The patch electrode pipette comes into contact with the membrane and a giga-seal is created between the pipette and the membrane by way of suction. An electrical signal is detected by an electrode in the patch pipette (col. 10, lines 1-2).

The apparatus of Olsen et al. does not expressly disclose that the cell is a cloned potassium channel expressed in Chinese hamster ovary cells.

Stephen et al. disclose a patch clamp device use to investigate the mechanism of action of the potassium channel blocker on a cloned potassium channel mouse expressed in Chinese hamster ovary cells (pg. 187, Abstract). The patch electrodes are from glass (pg. 188, left col., lines 40-45). The potassium channel mouse is expressed in Chinese hamster ovary cells (pg. 188, lines 24-37).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a cloned potassium channel expressed in Chinese hamster ovary cells as taught by Stephens et al. in the apparatus of Olsen et al. One of ordinary skill in the art

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would have been motivated to include a cloned potassium channel expressed in Chinese hamster ovary cells in the apparatus of Olsen et al. for the advantage of providing device to study the mechanism of action of a mammalian potassium channel (pg. 188, left col., lines 14-16). Since both Olsen et al. and Stephens et al. disclose a patch clamp device (Olsen: Abstract, col. 9, lines 57-67; Stephens: pg. 187, Abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
December 24, 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER